

Comments

The specification has been amended at paragraphs [0045], [0143], and [0162]. Claims 1, 2, 11, 12, 14-17, 21, 32, and 34-37 have been amended. All these claims have been amended to specifically recite the “A allele of G19524A.” The amendments add no new matter. Claims 3, 4, 6-10, 22, 26-31, and 41-51 have been cancelled. An Abstract of the Disclosure is attached at the end of this Response on a separate sheet.

Objections to the Specification

The Examiner objected to the specification. Specifically, the Examiner noted that the application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An Abstract has been attached to the end of this Response on a separate sheet. This Abstract contains no new matter.

Further, the Examiner objected to the disclosure because it contained embedded hyperlink and/or other forms of browser-executable code. Applicants have amended paragraphs [0045], [0143], and [0162] specifically to remove any embedded hyperlink and/or other browser-executable code. Thus, the Examiner’s objects have been noted, and the specification corrected.

Rejection under 35 USC 112, First Paragraph, Written Description

The Examiner has rejected claims 1-7, 11-27, and 32-44 under 35 USC 112 as allegedly not described in a way to reasonably convey that one is in possession of the claimed invention. More specifically, the Examiner erroneously alleges that the claims are drawn to methods of determining obesity or osteoporosis by detecting an extremely large genus of polymorphic variants of several different genes with any nucleotide content in any species of organism.

Contrary to the Examiner’s assertions, only the FRZB gene in humans is studied in the specification, and the claims are reasonably drawn only to that specific gene in humans. Despite the Examiner’s reference to the GeneCard for FRZB enumerating several homologs and expression variants among different species, only one single genomic sequence is referenced in the claims. Finally, the claims are not, as the Examiner asserts, drawn to predicting obesity or osteoporosis, but to “determining and individual’s risk for” obesity or osteoporosis. The distinction between the actual language of the claims and the Examiner’s description thereof is a significant one.

However, without acquiescing to the Examiners assertions and purely in order to expedite prosecution, the Applicant has amended the claims to read on the specific polymorphism elected in the Examiner's Election of Species Requirement mailed July 18, 2007, namely the A allele of G19524A. Thus the Examiner's assertion that the claims are broadly drawn to a large genus are no longer credible, and are moot. Thus, Applicant requests reconsideration and withdrawal of the rejection under 35 USC 112, first paragraph for Written description.

Rejection under 35 USC 112, First Paragraph, Enablement

The Examiner has further rejected claims 1-7, 11-27, and 32-44 as allegedly not enabled in a way such that one of skill in the art may practice the claimed invention.

While the Applicant can counter each of the enumerated *Wands* factors posed by the Examiner in the rejection, it is unnecessary to do so at this time.

As previously stated, without acquiescing to the Examiner's arguments, and purely to expedite prosecution, the claims have been amended to read on the A allele of G19524 of the human FRZB gene. The Examiner argument rely primarily on the mistaken interpretation of the claims being drawn to a large variety of polymorphisms among a large number of genes in a large number of species, both human and non-human. With the current amendment, those arguments are moot.

The Examiner further states that the specification provides no data for the association of the G19524A allele with an increase, decrease, protective, or predisposition for osteoporosis or obesity. To the contrary, the results in Tables 3 and 4, as well as the summary of the results in paragraphs [0166] and [0167] clearly show an association of the A allele of G19524A with obesity (as measured by BMI) and the G allele of G19524A with osteoporosis (as measured by incidence of vertebral fracture).

The Examiner further recites post-filing art of Kroese et al. ("Kroese") to assert that most conditions (such as obesity and osteoporosis) have several genetic components, and that there is no one single test that can conclusively predict a condition. The applicants must point out that Kroese does not contradict the ability of a single polymorphism to be able to predict risk to some degree. As stated before, the claims are not drawn to a method of conclusively predicting obesity or osteoporosis, but simply to "determining an individuals risk" for such conditions. It is accepted that such conditions have a variety of genetic factors, but this does not preclude using single polymorphisms in the predictions of risk.

The Examiner further cites the standard Patent Office references of Ionnidis , Hattersley et al. (“Hattersley”), and Hegele to generally disparage statistical studies and to teach that statistical association of such studies are highly inaccurate. These citations are, by and large, an indication of differences of opinion among the research community as to the meaning of statistical associations of polymorphisms, but are not persuasive in demonstrating that the claimed invention is not enabled. A person of skill in the art, even if skeptical of such associations, would still be enabled to practice the claimed invention.

Finally, the Examiner cites the post-filing art of Ikegawa et al. (“Ikegawa”) which cites two polymorphisms within FRZB. As these polymorphisms are outside the scope of the claimed invention, with the current claim amendments, Ikegawa is rendered irrelevant.

Thus, with the current claim amendments, the rejection under 35 USC 112, first paragraph, for enablement is moot. Applicant respectfully requests reconsideration and withdrawal of the rejection.

Conclusion

Applicants respectfully submit that this response is complete and responsive, and that the claims are in a condition for early consideration on the merits. In the event that a telephonic interview would be helpful, please contact the undersigned representative.

Under 37 CFR §1.136(a), Applicants respectfully request a 3-month extension of time to respond to the Office Action mailed March 21, 2008. The response date was June 21, 2008; with the granting of this request, the response time is re-set to September 21, 2008. The commissioner is hereby authorized to charge the fee due under 37 CFR §1.17(a)(3), to Deposit Account No. 50-0812. Please grant any additional extensions of time that may be required to enter this amendment and charge any additional fees or credit any overpayments to Deposit Account No. 50-0812.

Please direct all future correspondences to: Customer No. 22829.

Respectfully submitted,

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